

## **Exhibit C**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

|                         |                       |
|-------------------------|-----------------------|
| In re:                  | )                     |
| PHARMACEUTICAL INDUSTRY | ) CA No. 01-12257-PBS |
| AVERAGE WHOLESALE PRICE | ) MDL No. 1456        |
| LITIGATION              | ) Pages 1 - 119       |

CLASS CERTIFICATION HEARING

BEFORE THE HONORABLE PATTI B. SARIS  
UNITED STATES DISTRICT JUDGE

United States District Court  
1 Courthouse Way, Courtroom 19  
Boston, Massachusetts  
September 12, 2006, 10:25 a.m.

LEE A. MARZILLI  
CERTIFIED REALTIME REPORTER  
United States District Court  
1 Courthouse Way, Room 3205  
Boston, MA 02210  
(617) 345-6787

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## 1 APPEARANCES:

2 For the Plaintiffs:

3 THOMAS M. SOBOL, ESQ. and EDWARD NOTARGIACOMO, ESQ.,  
4 Hagens Berman Sobol Shapiro LLP, One Main Street, Cambridge,  
Massachusetts, 02142.

5 DONALD E. HAVILAND, JR., ESQ., The Haviland Law Firm,  
6 LLC, 740 S. Third Street, Third Floor, Philadelphia,  
Pennsylvania, 19147.

7 JEFFREY L. KODROFF, ESQ., Spector, Roseman & Kodroff,  
8 1818 Market Street, Suite 2500, Philadelphia, Pennsylvania,  
19103.

9 MARC H. EDELSON, ESQ., Hoffman & Edelson,  
10 45 West Court Street, Doylestown, Pennsylvania, 18901.

11 JENNIFER FOUNTAIN CONNOLLY, ESQ., The Wexler Firm, LLC,  
One LaSalle Street, Chicago, Illinois, 60602.

12 For the Defendants:

13 JOHN C. DODDS, ESQ., Morgan, Lewis & Bockius, LLP,  
14 1701 Market Street, Philadelphia, Pennsylvania, 19103-2921.

15 JAMES P. MUEHLBERGER, ESQ. and NICHOLAS PATRICK MIZELL,  
16 ESQ., Shook, Hardy & Bacon, LLP, 2555 Grand Boulevard, Kansas  
City, Missouri, 64108.

17 MICHAEL DeMARCO, ESQ. and AIMEE E. BIERMAN, ESQ.,  
18 Kirkpatrick & Lockhart Nicholson Graham, LLP, One Lincoln  
Street, State Financial Center, Boston, Massachusetts, 02111.

19 STEVEN F. BARLEY, ESQ., Hogan & Hartson, LLP,  
20 111 South Calvert Street, Suite 1600, Baltimore, Maryland,  
21202.

21 RICHARD D. RASKIN, ESQ., Sidley Austin, LLP,  
22 One South Dearborn, Chicago, Illinois, 60603.

23 JONATHAN REES, ESQ., Hogan & Hartson, LLP,  
555 13th Street, N.W., Washington, D.C., 20004.

24 KATHLEEN M. O'SULLIVAN, ESQ., Perkins Coie, LLP,  
25 1201 Third Avenue, 40th Floor, Seattle, Washington, 98101.

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## 1 APPEARANCES: (Cont'd)

2 For the Defendants:

3 ANDREW L. HURST, ESQ., Reed Smith, LLP,  
4 1301 K Street, N.W., Washington, D.C., 20005.

5 CHRISTOPHER C. PALERMO, ESQ., Kelley Drye & Warren, LLP,  
6 101 Park Avenue, New York, New York, 10178.

7 ELIZABETH I. HACK, ESQ., Sonnenschein Nath & Rosenthal,  
LLP, 1301 K Street N.W., Suite 600, East Tower, Washington,  
D.C., 20005.

8 DOUGLAS FARQUHAR, ESQ., Hyman, Phelps & McNamara, P.C.,  
9 700 13th Street, N.W., Suite 1200, Washington, D.C., 20005.

10 KIMBERLY D. HARRIS, ESQ., Davis Polk & Wardwell,  
450 Lexington Avenue, New York, New York, 10017.

11 PAMELA A. ZORN, ESQ., Sherin and Lodgen, LLP,  
12 101 Federal Street, Boston, Massachusetts, 02110.

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## 1 PROCEEDINGS

2 THE CLERK: In re: Pharmaceutical Industry Average  
3 Wholesale Price Litigation, Civil Action No. 01-12257,  
4 MDL No. 1456, will now be heard before this Court. Will  
5 counsel please identify themselves for the record.

6 MR. SOBOL: Good morning, your Honor. Tom Sobol  
7 for the plaintiffs.

8 MR. HAVILAND: Good morning, your Honor. Don  
9 Haviland here for the plaintiffs.

10 MS. CONNELLY: Good morning, your Honor. Jennifer  
11 Connelly for the plaintiffs.

12 MR. MUEHLBERGER: Good morning, your Honor. Jim  
13 Muehlberger on behalf of Aventis Pharmaceuticals.

14 MR. DeMARCO: Michael DeMarco for Aventis.

15 MR. DODDS: Your Honor, Jack Dodds for Pfizer and  
16 Pharmacia.

17 MR. BARLEY: Steven Barley for AmGen.

18 MR. RASKIN: Richard Raskin for Bayer Corp.

19 MS. BIERMAN: Aimee Bierman for Aventis.

20 MR. PALERMO: Chris Palermo for Dey, your Honor.

21 MS. (Inaudible): Good morning, your Honor.

22 (Inaudible) for Abbott Laboratories.

23 MS. HACK: Elizabeth Hack for Sicom  
24 Pharmaceuticals.

25 THE COURT: What are you doing all the way back

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1 there?

2 MS. HACK: There were no seats up there.

3 THE COURT: Does anyone want to be up here? I  
4 mean, I'm sure we could adjust the seats. It makes some  
5 sense. Mr. Alba, maybe we could move the witness chair down?

6 THE CLERK: Yes.

7 MS. HACK: Thank you so much.

8 THE COURT: All right. Is there anyone else who's  
9 way back there who wants to be somewhere else?

10 MR. FARQUHAR: Doug Farquhar for Watson. Can I  
11 just sit in the jury box?

12 THE COURT: Yes. No vote, but you go.

13 MR. REES: Good morning. Jonathan Rees for Aventis  
14 Behring.

15 MR. (Inaudible): Good morning, your Honor.

16 (Inaudible) for Baxter, and I'm happy to stay right here.

17 THE COURT: Okay. If you need to speak, just pop  
18 up because I might not notice you.

19 All right, now, because there are so many

20 attorneys -- and did I miss --

21 MR. HURST: Andrew Hurst, your Honor, for Fujisawa.

22 MS. O'SULLIVAN: Katie O'Sullivan for Immunex  
23 Corporation and also the defendants' liaison counsel in the  
24 states of Montana and Nevada cases, and we have a scheduling  
25 issue to bring to your attention at the end of this hearing.

|   |  |
|---|--|
| <p style="text-align: right;">Page 6</p> <p>1 THE COURT: Thank you. Anyone else?</p> <p>2 MR. DeMARCO: Your Honor, we missed one person. My 2</p> <p>3 colleague, Nick Mizell, in the corner will be operating our</p> <p>4 little slide presentation.</p> <p>5 THE COURT: Thank you. All right, now, because the</p> <p>6 Court Reporter probably didn't know about all of you, and</p> <p>7 just to make sure we have the correct people speaking, if you</p> <p>8 didn't sign a chart, make sure you stand up, and when you</p> <p>9 speak, identify yourself and the company that you're with.</p> <p>10 All right, so at this point we have a motion to</p> <p>11 certify the Track Two class. One thing is clear, that</p> <p>12 between Track One and Track Two, you all learned very well</p> <p>13 how to manipulate font, so that there's a huge amount in both</p> <p>14 of these briefs.</p> <p>15 MR. SOBOL: Less pages.</p> <p>16 THE COURT: Almost essentially 40, 50 pages of</p> <p>17 one-liners, both sides, so it was actually harder to follow</p> <p>18 than some of the previous briefs because there were so many</p> <p>19 different issues, and all the citations were put in mini-font</p> <p>20 in the footnotes, so that it really was chock-full of</p> <p>21 issues. I would urge you all, because there's no way in</p> <p>22 writing this I'm going to get through all of this, I'm not</p> <p>23 going to write and address every single point, so I really</p> <p>24 need people to focus on the primary issues that they want me</p> <p>25 to get through on the crosscutting issues as well as any</p> | <p style="text-align: right;">Page 8</p> <p>1 the plaintiffs' point of view.</p> <p>2 From the plaintiffs' point of view, after we went</p> <p>3 through Track One, the really material issues that needed to</p> <p>4 be gone through in terms of Track Two is adequacy and</p> <p>5 typicality of the proposed class representatives for the</p> <p>6 Track Two defendants, in that there was no need to rehash</p> <p>7 many of the issues, which, frankly, we believe that the</p> <p>8 defendants in their submission have sought to rehash from</p> <p>9 Track One. Those issues they seek to rehash are issues of</p> <p>10 TPP knowledge, of the extent to which physician-administered</p> <p>11 drugs are reimbursed on the basis of AWP, on the inability to</p> <p>12 crosswalk J-Codes --</p> <p>13 THE COURT: Can I say, I pretty much agree with you</p> <p>14 on Class 1 and 2. On Class 3, if I can remember my thought</p> <p>15 process when I certified it, that was, what was it, like over</p> <p>16 a year ago now, a year and a half ago?</p> <p>17 MR. SOBOL: Yes.</p> <p>18 THE COURT: It was a very raw record. Both sides</p> <p>19 had really focused primarily on the difference between</p> <p>20 self-administered and physician-administered drugs, with this</p> <p>21 area of third-party payors in the non-Medicare,</p> <p>22 physician-administered world being the weakest record. If I</p> <p>23 remember, in fact, people didn't even start focusing on it</p> <p>24 until the reply and the surreply. And it was, as far as I</p> <p>25 was concerned, the area that I understood the least, and I</p> |
| <p style="text-align: right;">Page 7</p> <p>1 individual -- for example, individual companies, it's just</p> <p>2 got to be the high point because I'm just not going to get</p> <p>3 through it all. All right.</p> <p>4 Mr. Sobol, you're the person who's moving. I think</p> <p>5 you'll be speaking, right?</p> <p>6 MR. SOBOL: Yes, your Honor.</p> <p>7 THE COURT: And was there a separate handout for</p> <p>8 you on this?</p> <p>9 MR. SOBOL: Yes, I do have a handout, your Honor.</p> <p>10 THE COURT: I have defendants' handout. I have</p> <p>11 two, right, from the defendants?</p> <p>12 MR. MUEHLBERGER: That's correct, your Honor. You</p> <p>13 have a joint submission and an individual</p> <p>14 defendant-by-defendant submission.</p> <p>15 THE COURT: Good, I have that.</p> <p>16 MR. SOBOL: There are two-handouts, your Honor.</p> <p>17 The first handout, your Honor, deals with one of the</p> <p>18 crosscutting issues, and the second handout is a chart which</p> <p>19 identifies the manufacturer, the class, and the drug coverage</p> <p>20 for the class reps. I have two copies of that, Robert.</p> <p>21 THE COURT: Thank you.</p> <p>22 MR. SOBOL: Your Honor, in my opening remarks, I'm</p> <p>23 only going to address one issue, and the reason I'm only</p> <p>24 going to address that one issue is because of the way that</p> <p>25 procedurally the Track Two issues get teed up, at least from</p>  | <p style="text-align: right;">Page 9</p> <p>1 thought the expert reports reflected the fluidity of the data</p> <p>2 at that point.</p> <p>3 So the question that I raise is, and I start off</p> <p>4 this way, suppose I certified 1 and 2 and waited to certify 3</p> <p>5 until after I had the trial?</p> <p>6 MR. SOBOL: Right.</p> <p>7 THE COURT: I'm going to learn hugely about that in</p> <p>8 a way that I wouldn't, and I could make certain judgments</p> <p>9 based on a fuller understanding of that record.</p> <p>10 Now, I understand that may create certain fairness</p> <p>11 issues for Track Two because you're not part of it, but it</p> <p>12 would give me a much deeper understanding of the issues.</p> <p>13 MR. SOBOL: Right. Nor is there any practical</p> <p>14 impediment to your doing that either in terms of our rush to</p> <p>15 get out notice on Track Two. That kind of thing, we just</p> <p>16 haven't scheduled anything with respect to it. And there's</p> <p>17 nothing that I can say, frankly, or the defendants can say in</p> <p>18 this context before you today on those issues that's going to</p> <p>19 be helpful, since you're going to be having a trial on that.</p> <p>20 All you will hear today are, you know, different views from</p> <p>21 an adversarial context in terms of what our positions are on</p> <p>22 that, when the reality is you're going to get a fulsome</p> <p>23 record later on on that, later on this fall.</p> <p>24 THE COURT: And I'm going to merge the Daubert</p> <p>25 hearing --</p>   |

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1 MR. SOBOL: You're going to merge the Daubert  
2 hearing. You're going to merge the summary judgment issues.  
3 There's going to be a bench trial. You're going to have four  
4 defendants litigating the same issues against the  
5 plaintiffs. You're going to hear testimony. And, frankly,  
6 it's something that's commonly done by judges who are trying  
7 to make decisions on class certification. Sometimes they'll  
8 have, in the personal injury context, for instance, they'll  
9 have sample trials. You know, they'll have exemplar trials.

10 THE COURT: This is something that struck me as  
11 they are all coming to the forefront at about the same time,  
12 and I wasn't sure how I would slow down the suit at all by  
13 waiting.

14 MR. SOBOL: I think, as a practical matter, you  
15 don't. For the practical issues that are before you, there's  
16 no date that you're scheduling that's, you know, critical  
17 path to make this decision between now and the end of the  
18 year or sometime when you've dealt with the trial.

19 THE COURT: All right, so I'll let you address all  
20 the issues on the merits, but it was certainly the pragmatic  
21 solution I was thinking about.

22 MR. SOBOL: Right.

23 THE COURT: All right, go ahead.

24 MR. SOBOL: And that's also one of the reasons why,  
25 your Honor, at least in my opening remarks, I'm not going to

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1 get into rebutting the defendants' issues in terms of  
2 knowledge, that kind of thing. I'm, frankly, just going to  
3 wait to hear what they have to say, figure out if there's  
4 anything that's germane to deal with that issue right now.

5 My cocounsel are going to deal with the specific  
6 issues about the coverage of the drugs, the class  
7 representatives and the adequacy and typicalities for Class 1  
8 and Class 2. To the extent that it becomes an issue for the  
9 Pipefitters Union here in Massachusetts for Class 3, I can  
10 deal with a couple of those issues.

11 It seems to me that there's really only one  
12 crosscutting issue that I want to put in its appropriate  
13 framework so the Court understands how this becomes relevant  
14 in Track Two and where it's not relevant in Track Two. And  
15 the buzz word for it, if you will, your Honor, ends up being  
16 the J-Code issue. And the issue, of course, vis-a-vis  
17 J-Codes is that for physician-administered drugs, it is quite  
18 common, as your prior decisions and as Dr. Berndt has pointed  
19 out and all the experts have pointed out, that the billing  
20 systems, both within Medicare and outside Medicare, use  
21 what's called a J-Code, which is a code that encapsulates  
22 sometimes, not always, many --

23 THE COURT: Is that a pun?

24 MR. SOBOL: Right, I didn't intend it, didn't even  
25 pick up on it, your Honor -- which includes numerous NDCs,

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1 sometimes by different manufacturers of different  
2 formulations of the same medicinal ingredient. And so the  
3 J-Code issue, the first point I want to make clear to you,  
4 your Honor, is this: It's important when we're talking about  
5 the ability to what people say "crosswalk," meaning either go  
6 from J-Codes to NDCs or go from NDCs to J-Codes, to  
7 understand the purpose for which one is trying to do the  
8 crosswalking. And I submit that there are at least three  
9 different ways in which the J-Code issue comes up in this  
10 track and in this case.

11 The three different ways are, first, for class  
12 representative purposes. I'll get to that in a minute.  
13 Second, for class membership purposes, which I'll get to in a  
14 second; and, third, for determining damages, or determining,  
15 in other words, the AWP reimbursement.

16 Now, let me deal with the third of those first.  
17 Sometimes the damage estimates that are undertaken in  
18 Track Two, and sometimes in Track One, will be for generic  
19 drugs. Oh, by the way, of course, the J-Code issue is really  
20 only a real issue when we're talking about generic and  
21 multi-source drugs. If you're talking about a single-source  
22 drug, the J-Code will show, implicitly has the information  
23 about the manufacturer because there's only one single  
24 source. So really the only time that the J-Code ends up  
25 crosswalking is just a matter of figuring out which J-Code

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1 applies to the NDCs for that manufacturer. It's single  
2 source for that manufacturer. You know what manufacturer it  
3 is. You don't have a J-Code issue for single-source drugs.

4 THE COURT: Talking basics, how many of these drugs  
5 in Track Two are the multi-source?

6 MR. SOBOL: It's about thirty or so. We'd have to  
7 actually go through it, and some of our charts show it. It's  
8 in approximately that amount, okay? There are significant  
9 number of multi-source drugs.

10 THE COURT: And how many of the single source?

11 MR. SOBOL: If you look at the chart that we've  
12 handed to you, your Honor, and there's a column called  
13 Drug Source, you'll see that, for instance, all the Abbott  
14 drugs are going to be multi-source. The AmGen drugs are all  
15 single source. The Aventis has some multi, some single. It  
16 goes on like that, okay? So rather than me giving you my  
17 off-the-cuff estimate, I would rely upon the chart.

18 THE COURT: So the reason this becomes more  
19 significant in this track, at least according to the  
20 defendants, is that there's a much larger percentage that are  
21 multi-source?

22 MR. SOBOL: There are more multi-source, which is  
23 why the defendants have tried to create more of an issue of  
24 the J-Code here than it was in Track One, correct.

25 THE COURT: Like Dey Labs is all one and --

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1 MR. SOBOL: Yes, and like Abbott is all  
2 multi-source, okay?

3 THE COURT: Okay.

4 MR. SOBOL: All right, so the J-Code issue is  
5 really only relevant, we suggest -- and I don't think the  
6 defendants really get into this -- only when we're dealing  
7 with the multi-source or the generic, not on the branded  
8 side, because walking back and forth is just comparing  
9 numbers.

10 So the three purposes -- we're just talking about  
11 the J-Codes now --- I'm going to deal with the last of those  
12 purposes, estimating damages. When we go back in time, your  
13 Honor, and we seek to estimate what people paid for a drug,  
14 the experts start with a J-Code, but they have to look to  
15 what the AWP's were associated for that J-Code back in time to  
16 be able to look at the, if you will, the scatter shot or the  
17 dispersion of the AWP's over time to then be able to determine  
18 what the mean was, what the Medicare reimbursement would have  
19 been under Medicare at that time.

20 THE COURT: So Medicare is the mean?

21 MR. SOBOL: Medicare uses the mean.

22 THE COURT: The mean.

23 MR. SOBOL: Okay? As you will see later on, later  
24 on it changes it. It says the mean of the AWP's or the  
25 branded lower, and I'll explain that a little bit but --

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1 THE COURT: Right, so that's the way the defendants  
2 represent it as --

3 MR. SOBOL: Yes. Yes, there's no dispute here so  
4 far, okay? I don't think, okay? And so for damage purposes,  
5 you have to go back and you have to look at how the AWP  
6 got -- what the reimbursement was, you have to crosswalk back  
7 to the AWP's, okay? And then once you get the AWP's, you can  
8 figure out what the AWP reimbursement was, we say in the  
9 aggregate for all payors, what the total average amount that  
10 all payors paid, and that's where the damages come in.  
11 That's one purpose for which you have to crosswalk.

12 Now, we submit that both Dr. Berndt has testified  
13 and submitted in his report that for later years, at least,  
14 2000 forward, that's easier to do, more feasible because of  
15 the robustness of the data that now exists. We've submitted  
16 the affidavit, the declarations of Dr. Hartman repeatedly in  
17 this litigation showing, both by way of his testimony and by  
18 way of example, that for later years and earlier years, he's  
19 been able to crosswalk back from the J-Code to the multiple  
20 AWP's, find out what the AWP reimbursement is, and be able to  
21 model damages. We have a declaration of Dr. Hartman.

22 We have examples, even from the defendants,  
23 Mr. Young, where he has actually undertaken crosswalking on  
24 an episodic basis for particular payors. We have an example  
25 that --

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1 THE COURT: I think defendants' point is often not  
2 that you can't do it; it's just extremely difficult and  
3 time-consuming the farther back you go.

4 MR. SOBOL: With respect to this purpose, okay,  
5 that may or may not be true, but we've demonstrated  
6 repeatedly that it can be and we have done it for these  
7 purposes, okay? For the purposes of number three that I've  
8 just told you about, estimating damages, we've done it. And  
9 I'm going to leave it like that. The defendants might have  
10 something to say about that. I'm going to leave the chance  
11 to rebut it because I've read their expert reports the  
12 defendants have recently submitted, and I think it again  
13 reinforces the fact that our expert, when estimating AWP  
14 reimbursement, historically has been able to do that  
15 extraordinarily accurately well. And while it may or may not  
16 be time and does, I mean, we have to pay the money, and it  
17 takes, you know, it takes effort to be able to do this, that  
18 it can be done.

19 The reason, of course, it has to be done is, there  
20 is no published what was the mean at any particular time and  
21 what was Medicare reimbursing at any particular time. That  
22 does not, as far as we know, exist historically. So this is  
23 something we have to go about and estimate rather than pull  
24 out as a number.

25 So if we move from that third purpose for which one

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1 crosswalks --

2 THE COURT: You've sought a class going back to  
3 1991.

4 MR. SOBOL: '91.

5 THE COURT: So is there a point in time at which  
6 this is not feasible?

7 MR. SOBOL: No. We have said that it is feasible  
8 for the whole time. Our expert actually focused on trying to  
9 do crosswalking for damage estimates pre-2000. He focused on  
10 the earlier time because he knew it was easier going forward  
11 and has been able to demonstrate that, and we don't think  
12 that it's difficult. From our point of view, what we need --

13 THE COURT: Well, it's difficult, but you say it's  
14 doable.

15 MR. SOBOL: It is doable. It is involved.  
16 Frankly, it is just involved. It's really not even all that  
17 complex, in the sense that you have to have the time and the  
18 patience to, within particular periods of time, isolate the  
19 AWP's that were out there for the drugs for that J-Code at  
20 that time, and you have to have the patience to be able to do  
21 that.

22 THE COURT: And are you conflating that discussion  
23 with figuring out which company was actually the source of  
24 the drug?

25 MR. SOBOL: No, I'm not, because for these



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1 purposes, for the number three purpose -- I haven't dealt  
2 with the other two -- for the number three purpose, what  
3 we're trying to do is, we're trying to figure out how the  
4 generic for multi-source was being reimbursed and in what  
5 period of time period of time, okay? And that's going to  
6 show how much the increase was for people at that time. So  
7 it doesn't matter to us which defendants' drug it was or it  
8 wasn't at any particular time. You need to know actually all  
9 of the AWP's at that time to be able to figure out what the  
10 mean reimbursement was for these purposes.

11 What we do then on the damages, so you can carry it  
12 through and understand, is we look at how much was being  
13 paid. That was the analysis we just talked about. And then  
14 for each separate manufacturer, we go into that  
15 manufacturer's data regarding what their actual average sales  
16 price was and how much they sold. And the damages that are  
17 applied to any one of the Track Two defendants is based only  
18 on the amount of drugs that they sold and the average actual  
19 sales price that they sold it at, being the difference  
20 between their company ASP and the mean for a generic, what  
21 was being reimbursed. Do you follow me?

22 As a result, no defendant is being charged in this  
23 case with having to pay damages for more than the drugs that  
24 they've sold and the amount to which their ASPs were below  
25 the mean of the AWP's that were out there. It's just their

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1 overcharges that they would be responsible for in terms of  
2 the ultimate damage figure.

3 THE COURT: Would it matter -- suppose they were  
4 the low AWP on the mean.

5 MR. SOBOL: Correct.

6 THE COURT: So are you overcharging them if you use  
7 the mean?

8 MR. SOBOL: No, because what we will have to do in  
9 proving the class trial is prove that, whether they're at the  
10 low of the mean or the high of the mean, we're going to have  
11 to prove that their contribution, their being close enough to  
12 the mean, caused the mean to stay there for reasons I'll get  
13 to in a minute. But the theory of liability, whether they're  
14 below the mean or above the mean, is that by being near the  
15 mean, they maintain that market of being at the mean. So  
16 what we're going to do is, we're going to have testimony, for  
17 instance, showing --

18 THE COURT: Why wouldn't you just give everyone the  
19 benefit of the doubt; if you can't figure out exactly which  
20 drug the guy took, take the low?

21 MR. SOBOL: Actually our expert does use, from a  
22 conservative point of view, he looks at the lowest of the  
23 reimbursable amount, so his numbers, his damages actually end  
24 up being conservative.

25 THE COURT: So your expert does take the lowest of

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1 the AWP?

2 MR. SOBOL: He doesn't take the lowest of all of  
3 the published AWP's, but my understanding is that when he is  
4 looking at where the mean is, he takes the lowest of the  
5 available choices to be able to take to be able to make sure  
6 that his number is conservative.

7 THE COURT: I'm not sure I fully understand it, but  
8 go ahead.

9 MR. SOBOL: Well, okay. So right before I move off  
10 this third purpose then, it's just important to, again, I  
11 want to emphasize this point: No defendant is being charged  
12 with sales beyond the sales that they made, okay.

13 Now, there are two other ways in which the J-Code  
14 issue crops up. It was as a class representative and then as  
15 a member of the class. Now, here the question is this: What  
16 the plaintiffs have done, with respect to the individual  
17 plaintiffs who are put forward as class representatives, is,  
18 for multi-source drugs, we have undertaken the efforts that  
19 we possibly can to be able to ID the drug that was actually  
20 injected into their body with a particular manufacturer.

21 Now, simply from claims data, with respect to any  
22 particular individual, it is very difficult for a  
23 multi-source drug to ID a manufacturer. It is in some  
24 situations possible, your Honor. How that "some situation"  
25 would be possible is if there is a -- well, it gets a little

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1 complicated, but there's a known scatter in terms of what the  
2 reimbursement rates are, and there is a particular charge  
3 that's put into the billing system. There are rare occasions  
4 where the claims data itself might be able to ID a  
5 manufacturer. But be that as it may, by and large, simply  
6 from claims data is extraordinarily difficult because all you  
7 have is the J-Code, and you don't know which of the  
8 manufacturers provided that particular product.

9 So for the class representatives, what we have done  
10 is made an effort to try to figure out which manufacturer's  
11 drug was injected into the class rep, and my colleagues are  
12 going to get into this. That's when you end up having to  
13 drill down into, for instance, physicians' records. You try  
14 to get records from the defendants who have provided the  
15 product to particular places, and if they've provided the  
16 product to a place where that class rep came from, then they  
17 may be able to ID it that way. We have a situation where  
18 somebody actually had a photocopy of the bottle or some kind  
19 of copy of the bottle, or that the medical records wrote in  
20 the name of the manufacturer or something like that. There  
21 are isolated situations like that.

22 Now, we don't think, however, that for purposes of  
23 this case, for a multi-source drug, on the basis of the  
24 liability claims that we've had, that we need to ID the  
25 injection that went into each person to a particular

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1 manufacturer for a multi-source drug in order for that class  
2 representative to be an adequate representative for the class  
3 or for people to be members of the class. And so I'd like to  
4 go to my slides now to be able to explain the reasons why,  
5 your Honor. The first slide --

6 THE COURT: Are there any companies with respect to  
7 which you cannot identify any person with certainty that  
8 bought a drug from the company?

9 MR. SOBOL: Yes, there's one company, Pfizer, which  
10 when we get into the details of this we can't identify. We  
11 haven't found a person who bought that J-Code, okay?

12 THE COURT: So with respect to all the other ones,  
13 you, at least, think that you've got at least one person --

14 MR. SOBOL: Yes.

15 THE COURT: -- from each class?

16 MR. SOBOL: Yes, the answer is "yes." There are a  
17 couple of classes where there's a hole here or there, which  
18 my cocounsel are going to point out, but the answer is  
19 "yes."

20 And so also, your Honor, if you can listen to the  
21 following sentence, and I hope I get this out right, this is  
22 our position vis-a-vis class representatives and membership:  
23 If a class representative paid a co-pay for a J-Code sold by  
24 a defendant, then that plaintiff has purchased a product  
25 based upon the defendants' AWP. I'm going to come back to

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1 that when I go through this, but that is our position.

2 THE COURT: And you're saying the only defendant  
3 for whom that's absolutely dispositive is Pfizer?

4 MR. SOBOL: Correct, because we do not have a  
5 plaintiff, Pfizer, as opposed to its subsidiary, Pharmacia,  
6 so Pfizer standing alone has only one drug in this case,  
7 Zythromax.

8 THE COURT: What is that?

9 MR. DODDS: It's an in-hospital antibiotic.

10 MR. SOBOL: There is no class representative for  
11 whom we have purchased on the basis of a J-Code, or any  
12 basis, Zythromax, so Pfizer would be out.

13 THE COURT: Well, let me ask you this. Counsel  
14 just identified that as an in-hospital antibiotic. Is that  
15 the possible explanation -- Mr. Dodds, I'm sorry, is that  
16 right?

17 MR. DODDS: Yes, your Honor, that's correct.

18 THE COURT: Is that the explanation? Is it only  
19 administered inside a hospital?

20 MR. DODDS: I don't know that it's never  
21 administered outside the hospital, but typically it's given  
22 to people in-hospital to fight infection.

23 THE COURT: And so that's a different payment  
24 scheme, right?

25 MR. DODDS: Correct. That's Medicare Part A.

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1 THE COURT: Would that be the reason?

2 MR. SOBOL: It's a large part of the reason, yes,  
3 your Honor. I think there's also lots of reasons why it is  
4 we've had difficulty finding -- you know, people dying out in  
5 this class, you know, for --

6 THE COURT: People?

7 MR. SOBOL: People who have been dying out of this  
8 class, we've had two or three class representatives who have  
9 died, you know, within the past twelve, fourteen months too,  
10 so --

11 THE COURT: Sure. Well, how do you know it's a big  
12 issue for you if mostly it's administered in a hospital? In  
13 other words --

14 MR. SOBOL: Well, I think that that can be said,  
15 you know, mostly or not. I don't know the breakdown for  
16 Zythromax. Even, for instance, Kytril and Zofron, it's  
17 provided in hospitals, it's provided in clinical settings,  
18 it's provided in other kinds of settings. You know, each of  
19 these drugs have different profiles, if you will, of where it  
20 is that they tend to be used more than others; but it's not  
21 as if, I mean, it's just been acknowledged, you can find no  
22 drug that, you know, reimbursed Medicare Part B for  
23 Zythromax. But we don't have a class representative who has  
24 purchased on the basis of the J-Code for Zythromax, and  
25 therefore Pfizer would be out.

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1 THE COURT: So I should just dismiss them out right  
2 now?

3 MR. SOBOL: No.

4 THE COURT: On the consumer class. So do you have  
5 third-party payors?

6 MR. SOBOL: We do not.

7 THE COURT: You have no one for Pfizer?

8 MR. SOBOL: Correct. So you would deny the  
9 Track Two class certification with respect to it.

10 THE COURT: So he can go home?

11 MR. DODDS: I'm doing really well so far, your  
12 Honor. I'm happy with how things are going so far.  
13 (Laughter.)

14 THE COURT: I mean, is that the bottom line?

15 MR. SOBOL: Well, I think that, you know, if the  
16 situation doesn't change, that will end up being the bottom  
17 line. I think that the only action you need to take today  
18 is, you deny class certification with respect to Track Two as  
19 to Pfizer as opposed to Pharmacia, its subsidiary.

20 THE COURT: Are you representing Pharmacia as  
21 well?

22 MR. DODDS: I am, your Honor, yes.

23 THE COURT: Okay, so you're not out so fast.

24 MR. DODDS: Not quite.

25 THE COURT: Okay, thank you.



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1 MR. SOBOL: So going then to my slides, your Honor,  
2 we don't have to focus on the first slide because that's the  
3 J-Code issue with respect to single source, which I've  
4 already addressed.

5 Now, with respect to multi-source drug, our  
6 position is that the Medicare co-payment for a J-Code will  
7 also qualify as class membership, and that crosswalking from  
8 J-Codes, this is more feasible for the later time than the  
9 earlier time. That's with respect to the ability to do  
10 damages.

11 And on Page 4, your Honor, I have the quote from  
12 Dr. Berndt that acknowledged that, and then on Page 5 another  
13 quote that acknowledged that. And, of course, also just as a  
14 reminder before I go on to this point, your Honor, on Page 6  
15 we've even indicated that this dispute between the experts,  
16 between Young on the one hand and Hartman on the other hand,  
17 as to whether or not J-Code crosswalking for purposes of the  
18 damage analysis was possible was the kind of issue that  
19 you're going to deal with in the context of a Daubert  
20 hearing, not in the context of class certification. So we  
21 don't think that J-Code crosswalking vis-a-vis the damages  
22 analysis is anything that you have that's relevant for your  
23 purposes today.

24 THE COURT: All right, so let me stop you there.  
25 So would it make sense for me to defer class cert on all of

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1 that ends up being the kind of wrongful conduct that  
2 increases the overall --

3 THE COURT: Well, actually, that's why I asked you  
4 that question. So before when you said the mean, it really  
5 wasn't the mean? It was the median?

6 MR. SOBOL: Right, it was the median, correct.  
7 Thank you. You got me.

8 THE COURT: So on the median, don't the outliers  
9 get carved off, as I remember?

10 MR. SOBOL: No. Actually, what the carriers do is,  
11 they'll actually pick one particular AWP, which they'll call,  
12 although it should be the -- well, in any event, they do pick  
13 the one that is in the middle, from what I understand, okay?  
14 Here we know that whether it's the median or the mean --

15 THE COURT: Does the statute say? Isn't there a  
16 statute that deals with --

17 MR. SOBOL: It says the median.

18 THE COURT: What?

19 MR. SOBOL: It says the median.

20 THE COURT: The median.

21 MR. SOBOL: Yes.

22 THE COURT: Okay.

23 MR. SOBOL: Here we know that those defendants that  
24 are publishing AWP's that are higher are contributing to a  
25 higher median. We also know because we have evidence, and as

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1 the classes until I did Daubert in the context of the trial  
2 in November?

3 MR. SOBOL: No, I don't think -- again, I don't  
4 know -- the practical issue is that I don't know of a  
5 critical path issue you have right now vis-a-vis Track Two,  
6 getting any of the class issues done. However, I don't think  
7 there's much more education that you need in terms of being  
8 able to certify Track Two right now, have whatever appellate  
9 issues may or may not arise with respect to that, if now is  
10 when they want to deal with it, okay, with respect to the  
11 other issues for the reasons I'm about to get into, because  
12 the only issues we think that are relevant to you today is  
13 typicality and adequacy. I'm dealing with the J-Code issue  
14 now on my first two points, class membership and class  
15 representatives, for the J-Code issue, and now I'm on Page 7,  
16 your Honor.

17 Our position with respect to the defendants'  
18 wrongful conduct by the generic companies, when they post  
19 high AWP's, is that there is a series of different ways in  
20 which their conduct contributes to -- how their AWP  
21 manipulation contributes to the median. The first, of  
22 course, is the classic one: "Defendants impacting the median  
23 through AWP perhaps," meaning if they're actually publishing  
24 AWP's, and they frequently do -- in fact half the time they do  
25 by definition publish AWP's that are higher than the median --

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1 you've indicated in your prior decisions, that when generic  
2 companies are leapfrogging each other vis-a-vis AWP's, that  
3 kind of conduct also, whether they're the one that's being  
4 leapt over or they're last or they're the one that leaped  
5 over earlier, affect the median.

6 We also know this, your Honor -- this is in our  
7 brief, and it's also in Dr. Hartman's declarations  
8 repeatedly -- that the defendants maintain high AWP's. Just  
9 by maintaining high AWP's in a buckshot area, if you will,  
10 even if you're below the median, even you're below the mean,  
11 even if you're below the average, if you are maintaining your  
12 AWP's in a high area, what you end up doing is having what our  
13 expert calls and what's called usually a Nash equilibrium,  
14 meaning that you're keeping all of the same spots up in the  
15 same area, and you haven't actually told the truth. If one  
16 of them tells the truth and drops way down to where the  
17 reality is on the average selling price, that ends up being a  
18 huge signal to Medicare, and possibly to private reimbursers,  
19 that there must be something wrong with all the other AWP's.  
20 And by a company failing to report the truth, it perpetuates  
21 the median up where it is, even if that particular  
22 defendant's AWP happens to be somewhat less than some of the  
23 other defendants.

24 Now, this we know from the pleadings and from the  
25 declarations of Dr. Hartman, and from what has happened

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1 before CMS and Congress, is not just theory but reality. I'm  
 2 going to skip ahead for a moment, your Honor, to the next  
 3 page. Your Honor will recall that from '92 to '97,  
 4 multi-source generics were reimbursed at the lower of EAC, or  
 5 the MAC, where the MAC is defined as the median of AWP. Then  
 6 what happened in and around 1996 or 1997, your Honor, is that  
 7 there was this Nash equilibrium for --

8 THE COURT: And EAC was AWP or not? What was EAC?

9 MR. SOBOL: It was the estimated acquisition cost.  
 10 It didn't happen.

11 THE COURT: In effect, that's what you've always  
 12 claimed didn't happen?

13 MR. SOBOL: Right.

14 THE COURT: Okay.

15 MR. SOBOL: Okay? In or around 1996 or 1997, for a  
 16 particular drug, your Honor -- and I apologize, I don't  
 17 recall exactly what it is -- there was this Nash equilibrium  
 18 where there was a branded and a bunch of generics that all  
 19 had their AWP's up around the same point. What happened is, a  
 20 branded company chose to tell the truth and dropped its AWP  
 21 down to where ASP was. And all of a sudden, given this  
 22 formula, there was this aberration out there in the  
 23 marketplace because the reimbursement was being forced to be  
 24 at the median of the AWP's for all generic forms. But the AWP  
 25 for the branded was much less. By a branded company in this

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1 particular situation having told the truth, the signal came  
 2 out that the other AWP's must be wildly wrong; why are we  
 3 paying so much more for generics when you can get the branded  
 4 for less?

5 So what happened was -- and we've already skipped  
 6 to the page -- on Page 9, the whole system had to be changed  
 7 to deal with that. And what happened was, they said the  
 8 lesser of, and then you can have the old formula, or the AWP  
 9 of the least expensive brand name drug. And, again, this is  
 10 in Dr. Hartman's reports. It's also in, you know, our  
 11 briefing, that kind of thing.

12 But, you know, going back to my Page 7, the notion,  
 13 we think, that when one of these defendants -- and we're  
 14 going to intend to obviously prove this at the trial that's  
 15 coming up for their generics and later on -- when one of  
 16 these defendants are publishing AWP's that are high, sometimes  
 17 they're going to be higher, sometimes they're going to be  
 18 lower or whatever, even when they are lower, they impact the  
 19 ultimate reimbursement level by playing a game along with  
 20 other people -- it's not a conspiracy -- it was the Nash  
 21 equilibrium -- that's something different -- but when they  
 22 play the game of not telling the truth, they're impacting the  
 23 median reimbursement.

24 So from our point of view then, anybody who pays on  
 25 the basis of a J-Code, for instance, for albuterol, if

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1 they've paid for albuterol on the basis of that J-Code,  
 2 whether it was Schering or Abbott or some other defendant,  
 3 it's the defendant's drug who they actually got injected into  
 4 them, that payment was based upon the conduct of the  
 5 defendant, whether it was Schering or Abbott, because that  
 6 median was based upon the combined effort of the fact that no  
 7 one in that Nash equilibrium was telling the truth.

8 So there are other things, of course, that by the  
 9 defendants' failing to report true AWP's, that affects the  
 10 median. It's the point I just made.

11 Also the point is this, your Honor: There's been a  
 12 question that's been raised by the defendants about, "Well,  
 13 if it's the median, we don't have any motive to be having  
 14 high AWP's. We have no reason to have that motive at all."  
 15 We've dealt with that extensively in our brief, how it is  
 16 that that's belied by their own conduct and by their own  
 17 internal documents.

18 But it also is the case this, your Honor, and  
 19 sometimes we lose sight of this: Medicare reimbursement  
 20 Part B isn't the only place where generic drugs get  
 21 reimbursed. Generic drugs get reimbursed also by private  
 22 payors, which are usually but not always MAC'd. Sometimes  
 23 those private payors may end up in certain circumstances  
 24 reimbursing on the basis of AWP for some reason. Medicaid  
 25 sometimes might reimburse on the basis of AWP a

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1 physician-administered drug. There are all sorts of other  
 2 possible reasons that might creep through so that a defendant  
 3 might have a motive, not in Medicare Part B but somewhere  
 4 else, to be having a high AWP. And by posting that high AWP,  
 5 they can take advantage in that other reimbursement area, but  
 6 by posting it also, they have affected the Medicare Part B  
 7 median.

8 That is the only explanation, by the way, your  
 9 Honor, if the defendants, even if Medicare Part B  
 10 religiously, for all multi-source drugs, religiously  
 11 reimbursed on the basis of the median, that there were no  
 12 exceptions within that, why it is that there are some very  
 13 high AWP's that are out there for some generic manufacturers.  
 14 It can't be just because they willy-nilly do it, that kind of  
 15 thing. There has to be a reason. The defendants have never  
 16 come forward with a reason as to why they engage in this or  
 17 why their documents say that they're doing this.

18 THE COURT: There's been extensive discovery at  
 19 this point, so do you have a private payor saying, "We simply  
 20 accepted the AWP in these multi-source areas"?

21 MR. SOBOL: I cannot -- I have seen situations,  
 22 your Honor, although candidly I can't give you the specific  
 23 examples right now, where I've seen situations where for one  
 24 reason or another, you have a payor in a particular situation  
 25 reimbursing a generic on the basis of AWP.

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1 THE COURT: So most of them pick up this median  
2 concept, is that right? The third-party payors, how do they  
3 reimburse?

4 MR. SOBOL: For generics, for these drugs, they  
5 reimburse also on the basis of a MAC.

6 THE COURT: Right.

7 MR. SOBOL: Yes, for the most part, for the most  
8 part.

9 THE COURT: So I'm not understanding your point.  
10 Why would it --

11 MR. SOBOL: Well, because it not always works like  
12 that. In other words, there are exceptions to the rule.

13 THE COURT: And can you think of one right now?

14 MR. SOBOL: I honestly can't, your Honor.

15 THE COURT: All right, I understand. All right.

16 MR. SOBOL: So I want to make sure if I go  
17 through a --

18 THE COURT: You know, we just don't have the  
19 rest -- so are you pretty much --

20 MR. SOBOL: I'm pretty much done. I just want to  
21 wrap up this point then, okay? The point that I'm trying to  
22 make with respect to this is: If somebody has bought on the  
23 basis of a J-Code, they have been impacted by Abbott's  
24 wrongful conduct or Schering or whoever else manufactures  
25 that J-Code, but that's our position on that.

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1 I also want to point out too, your Honor, that if  
2 you go to my Slide 10, "Abuse of AWP's in the multi-source  
3 context for Medicare Part B shows that all purchasers of the  
4 J-Code multi-sourced drug are impacted similarly by the same  
5 median price." In other words, we think the class  
6 certification is more amenable here where you have people all  
7 being impacted by the median price.

8 The other thing that's interesting about this, your  
9 Honor, is that you remember Dr. Berndt in his report. One of  
10 the things that he made clear several times -- I'm not going  
11 through the slides, but I have them in here -- is, Dr. Berndt  
12 pointed to three or four features of the physician-  
13 administered drug area that he thought contributed to why  
14 there's all this fraud and abuse capability with respect to  
15 physician-administered drugs. He talked about how there was  
16 a lack of transparency. There was a couple of other things  
17 throughout there. And one of the things he focused on is, he  
18 said, you know, the fact that there are J-Codes that are used  
19 in this area is something that creates a lack of transparency  
20 for manufacturers to be able to engage in fraud and abuse of  
21 the reporting, because even the third-party payors, even the  
22 sophisticated ones like Aetna and Humana and Cigna and  
23 Wellpoint and that kind of thing, because the  
24 physician-administered area is happening on the basis of  
25 J-Codes, they can't see and they don't know as much

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1 information as they otherwise would. So what Dr. Berndt  
2 concluded is that the J-Code issue is a source of the system  
3 that enables the defendants to engage in the wrongful conduct  
4 that is before you in this case.

5 It is ironic, therefore, that the defendants try to  
6 say, "Because we have some anonymity in the J-Code area,  
7 which is a source for our fraud and abuse, you can't certify  
8 a class. Because you're never going to be able to find out,  
9 you know, which company's albuterol was taken by that elderly  
10 cancer patient twelve years ago, don't certify the class."

11 That's what they hinge a very significant part of their case  
12 on, the anonymity in the system that they've sought to and  
13 have, we allege, abused, and even which Dr. Berndt -- and  
14 this is Dr. Berndt's point -- they are trying to use as a  
15 basis upon which to have you deny class certification to  
16 people who are ripped off for generic pharmaceuticals. We  
17 don't think that that's appropriate.

18 THE COURT: You know, this isn't the first time the  
19 courts have struggled with this issue. I'm thinking out  
20 loud. I remember in the lead paint industry, there was an  
21 issue of who manufactured the paint in an older home. Do you  
22 remember where that case law played out?

23 MR. SOBOL: Yes. In Massachusetts, it's the  
24 Payton Labs case which we've cited in our brief. That was a  
25 DES case, your Honor, involving a drug that is manufactured

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1 by more than one manufacturer. There, given the kind of  
2 theory that the plaintiffs put forward, the SJC said, "Well,  
3 we can't go forward with that kind of theory," but at the end  
4 of its opinion it gave a road map as to how it is that you  
5 would impose essentially market share liability. And one of  
6 the critical features they said is, you can't be having one  
7 of the defendants pay more than their fair share, more  
8 than -- you know, they can't come forward and have to pay a  
9 hundred percent of one person's damages if their market share  
10 was only 20 percent or something like that.

11 THE COURT: Is that an appropriate model to think  
12 about, even though I know it's not binding on me in a class  
13 cert?

14 MR. SOBOL: It's not binding. It's an appropriate  
15 analogy --

16 THE COURT: Well, actually, going back to  
17 Erie V. Tompkins, is this a substance or a procedure issue?

18 MR. SOBOL: Well, actually, I don't think it -- to  
19 me, what it is is this: Our case here is more compelling.  
20 There it's a personal injury case, right, where by definition  
21 you know that the defendant's product may or may not have  
22 caused the harm. That's the issue in Payton Labs. That's  
23 the issue in the lead paint case. You don't know if the  
24 defendant's wrongful conduct caused the plaintiff harm, but  
25 you still might hold them liable. And the courts have said,

|  |   |
|--|---|
| <p style="text-align: right;">Page 38</p> <p>1 "Even in a situation where you know that the defendant's<br/>2 wrongful conduct caused them harm, we might find them harmful<br/>3 for their contribution."<br/>4 Here we don't have that. Here we know that even if<br/>5 the plaintiff got Schering's albuterol or Warrick's albuterol<br/>6 or Abbott's albuterol, their overpayment was still in part<br/>7 based upon Schering's and Abbott's or Warrick's wrongful<br/>8 conduct.<br/>9 THE COURT: But what if -- I'm thinking out loud,<br/>10 which is what if one only had 10 percent of the market and he<br/>11 only had 90 percent of the market?<br/>12 MR. SOBOL: Right. So it would still be based upon<br/>13 their wrongful conduct, but then you go back to my earlier<br/>14 point. Our damage model only seeks to hold them liable to<br/>15 the class as a whole for their sales, so they're never being<br/>16 asked to pay more than their fair share. It would be<br/>17 different -- our damage model could have, your Honor, sought<br/>18 to impose liability upon, for instance, Warrick for all<br/>19 overpayments of generic drugs regardless of their sales<br/>20 because they contributed to a higher median for everybody.<br/>21 That's not our damage model. Instead, we only seek to have<br/>22 the overcharges associated with respect to Warrick's sales,<br/>23 so it never has to pay the class of harmed people more than<br/>24 its fair share.<br/>25 THE COURT: Thank you. Now, let's --</p>   | <p style="text-align: right;">Page 40</p> <p>1 you had any questions that were directed specifically to the<br/>2 individuals, their counsel could stand up and give you a<br/>3 couple of minutes.<br/>4 Failing that or without that, I believe most of the<br/>5 defendants here -- I'm supposed to, I think, speak for most<br/>6 of them at this point -- are willing to rest on their papers<br/>7 and the demonstratives that we've provided to you.<br/>8 THE COURT: Okay, so let's just deal with the<br/>9 crosscutting issues, and to the extent that I get completely<br/>10 confused once I've resolved the crosscutting ones, I can call<br/>11 in that counsel and plaintiffs' counsel and --<br/>12 MR. DeMARCO: We'll go from there and figure it<br/>13 out.<br/>14 THE COURT: That's what took enormous amounts of<br/>15 time last time.<br/>16 MR. DeMARCO: Yes, trying to keep a little bit of<br/>17 order to the process.<br/>18 THE COURT: Okay, good.<br/>19 MR. BARLEY: Your Honor, I'm standing because I<br/>20 represent AmGen, and I would like to address one or two<br/>21 issues that are unique to our company and how we present in<br/>22 the papers. I think I'll be five or ten minutes at the most.<br/>23 THE COURT: I will try, and if for some reason we<br/>24 don't get there, we could just -- where are you from?<br/>25 MR. BARLEY: I'm from Baltimore.</p> |
| <p style="text-align: right;">Page 39</p> <p>1 MR. DeMARCO: Your Honor, just to put some<br/>2 perspective on the arguments today --<br/>3 THE COURT: Yes, I'd love to hear from you, but let<br/>4 me just ask, does this make sense? I imagine at some<br/>5 point -- well, last time around when I got into the duking it<br/>6 out whether Mr. Bean did or didn't take X, the argument<br/>7 didn't help me very much. I literally needed to roll up my<br/>8 sleeves and actually walk through the documents. So do you<br/>9 all want to have that kind of argument class rep by class rep<br/>10 or rest of your papers?<br/>11 MR. DeMARCO: Well, this is what we thought might<br/>12 help you out because I know that we're working toward an<br/>13 efficient presentation here. There are two principal<br/>14 speakers today to my right and left, Jack Dodds who you may<br/>15 remember from past times is a RICO man -- today he's a<br/>16 consumer man -- and Jim Muehlberger who's going to argue the<br/>17 TPP issues. Then the reason we submitted two little booklets<br/>18 to you is that one of them is the slides that we expect to<br/>19 use for the joint opposition, which are the so-called<br/>20 crosscutting or the joint issues that my colleagues will<br/>21 argue. Then you have another booklet that addresses every<br/>22 defendant, all thirteen defendant organizations. Each of<br/>23 them, I suspect most of them, are represented by counsel here<br/>24 today. We thought that after you heard the principal<br/>25 speakers and get into whatever you were going to get into, if</p> | <p style="text-align: right;">Page 41</p> <p>1 THE COURT: So if worse comes to worst, that's only<br/>2 a shoot up the coast, we'll just do another hearing. It's<br/>3 not like someone's coming across country.<br/>4 MR. HURST: Your Honor, we're found in the same<br/>5 position. I think actually some of our presentation, about<br/>6 90 seconds, might add a lot of color to the things you're<br/>7 talking about, but we're in the same position as AmGen.<br/>8 THE COURT: Where are you from?<br/>9 MR. HURST: We're from south of Washington, D.C.<br/>10 THE COURT: Not from Japan, right?<br/>11 MR. HURST: Oh, no, no.<br/>12 THE COURT: Is there anyone from some incredible<br/>13 location that couldn't come here easily again on an<br/>14 individual issue? All right, fine.<br/>15 MR. DeMARCO: Okay? So Jack will address the first<br/>16 issue for the defendants.<br/>17 THE COURT: I'd forgotten that you were a RICO man.<br/>18 MR. DODDS: Your Honor, I was, and that was a very<br/>19 long time ago, your Honor.<br/>20 THE COURT: It was.<br/>21 MR. DODDS: I was RICO man. Now I'm a different<br/>22 person, your Honor. Now I am, simply put, "If you certify<br/>23 these classes, you'll be committing reversible error" man.<br/>24 THE COURT: All right.<br/>25 MR. DODDS: And I understand that when your Honor</p>  |



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1 came out, you said that you pretty much agreed with Mr. Sobol  
2 as to Classes 1 and 2, so I'm fighting an uphill battle a  
3 little bit here, but I'd like to try to fight it anyway  
4 because I think I'm right.

5 THE COURT: Well, it was with respect to -- not  
6 with respect to this last proposition of his.

7 MR. DODDS: Sure, understood.

8 THE COURT: It was with respect to commonality, and  
9 I'm not going to revisit anything that I did last time unless  
10 I have a really good reason for doing so, so -- but this  
11 issue is different because he's basically asking me, and  
12 that's the new piece here, is to take the standing point, and  
13 that's different.

14 MR. DODDS: Well, your Honor, I want to make one  
15 point, and then I'll turn precisely to what Mr. Sobol said.  
16 I can understand why, your Honor, with all the work that  
17 you've done and with all the work that went into Track One,  
18 why you would think you've already addressed commonality,  
19 predominance, superiority, ascertainability, as you're  
20 required to do. The fact of the matter is, your Honor, with  
21 respect to the classes as they're defined here and the class  
22 reps as they're set forth here, you actually have not done  
23 that because you've never really had an opportunity to do  
24 it.

25 You will recall, your Honor, the procedural posture

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1 in which this thing came to you when the motion for class  
2 certification in Track One was presented, and it's especially  
3 important with respect to Class 1. You had no individual  
4 plaintiffs. You had no individual class reps. Remember when  
5 I first stood up here, your Honor, as RICO man, I raised the  
6 standing issue for the first time. I raised the issue  
7 because in the first complaint there were individual  
8 plaintiffs named, people. And I made the point that the  
9 plaintiffs had not alleged that any of those people, with one  
10 exception, used the drug manufactured by any of the  
11 defendants in the case, and that therefore they lacked  
12 Article III standing.

13 Now, plaintiffs' counsel stood up at that time and  
14 said -- I think it was Mr. Kodroff stood up and said, "Well,  
15 your Honor, it was a drafting error." And that's how I  
16 remembered it. I went back and looked at the transcript, and  
17 that's what happened. And your Honor gave them leave to  
18 amend because they said, if they had leave to amend, they  
19 could name individuals with standing. So they amended, and  
20 there were no individuals. There were associations and I  
21 believe TPPs at that time, or maybe associations and  
22 community groups, but there were no individuals. And that's  
23 how the case proceeded up until the motion for class  
24 certification was presented. The proposed class reps were  
25 the associations and the TPPs for Class 1, for the Medicare

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1 Part B class. So there was no discovery of any individual  
2 class reps.

3 THE COURT: Right, and then I agreed with  
4 defendants, and I made them come up with individuals and  
5 knocked some claims out where there weren't individuals.

6 MR. DODDS: Correct, and individuals were -- but  
7 what your Honor did in the opinion was, your Honor made  
8 findings with respect to things like predominance and  
9 superiority based on, I submit, your Honor, assumptions  
10 because that's all you had at the time. You didn't have a  
11 record from which you could make a judgment about whether  
12 those things were satisfied as to individual Medicare Part B  
13 class representatives.

14 THE COURT: I remember going through stacks.

15 MR. DODDS: You had a huge record at the time that  
16 related to the class reps that were presented to you, none of  
17 whom were individuals at the time that you made those  
18 findings, your Honor, none of whom were individuals.

19 THE COURT: I'm not sure I remember it that way,  
20 but go ahead, why don't we go on to this case.

21 MR. DODDS: Sure, and your Honor can go back and  
22 check the record, and you'll see that that is in fact the  
23 case. Your Honor said in the opinion that because plaintiffs  
24 claimed that they had individuals, their words, and in your  
25 Honor's opinion in your words, "waiting in the wings," you

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1 would certify the class subject to them going and finding the  
2 individuals.

3 THE COURT: Right.

4 MR. DODDS: And you made findings about things like  
5 superiority and predominance.

6 THE COURT: Right, and then they found the  
7 individuals, and then I had stats about each individual.

8 MR. DODDS: Correct, and the only issues that were  
9 litigated beyond that point were whether the individuals had  
10 standing, whether there was adequacy and typicality. That  
11 was all that was litigated after that point. The issues like  
12 predominance, superiority, and ascertainability were never  
13 litigated, if your Honor goes back and looks at the record,  
14 with respect to Class 1.

15 And here's the reason why it's important, your  
16 Honor, and Mr. Sobol actually in one of the statements that  
17 he made highlights the problem. Mr. Sobol said -- and this  
18 was with respect to the generics issue, but it cuts across  
19 the entire, all of these classes, and it exists for generics  
20 and for single-source drugs -- Mr. Sobol said that one of the  
21 reasons that this crosswalk had to be done was to identify  
22 who the class members were, that what he called that detailed  
23 and intricate crosswalking would need to be done in each  
24 instance for a multi-source drug to identify who the class  
25 member was.



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1 Your Honor, our position on this is very, very  
2 simple. Under the First Circuit's decision in Crosby and  
3 which is cited toward the end of our brief, it would be  
4 reversible error for your Honor to certify a class when the  
5 class members can only be identified through individual  
6 fact-finding and individual litigation, and the record your  
7 Honor has before you now shows that that is precisely what  
8 has to happen here.

9 With respect to the --

10 THE COURT: Because of the J-Code problem?

11 MR. DODDS: Not just because of the J-Code problem,  
12 your Honor, not just because of the J-Code problem; because  
13 of the fact that, I think as Mr. Sobol said during the class  
14 notice hearing, more than four out of five Medicare Part B  
15 beneficiaries don't make any co-pay out of their pocket at  
16 all. The vast majority of Medicare Part B beneficiaries make  
17 no co-pay out of their own pocket.

18 THE COURT: Right.

19 MR. DODDS: Okay. Then you have those who do make  
20 some payment out of their pocket.

21 THE COURT: Right.

22 MR. DODDS: The record that your Honor has before  
23 you now, and as you go through the individual defendant's  
24 submissions, as you roll up your sleeves and go through this  
25 defendant by defendant, you will see that identifying the

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1 people who paid out of their own pocket, where that payment  
2 was based on AWP, which is what has to happen to meet the  
3 class definition here, is an intensely -- is a very --

4 THE COURT: You know, the defendants put together  
5 this fabulous tutorial for me, as did the plaintiffs, really  
6 early on in the case. I remember sitting at home and just  
7 watching the video.

8 MR. DODDS: Yes, your Honor.

9 THE COURT: And basically everyone conceded that  
10 AWP was the benchmark in the industry. Now, it may be that  
11 the theory of the case is shifting, and there may be some  
12 instances where it isn't, and that might be a fact issue, but  
13 it is a sea change shift as to how the defendants have been  
14 characterizing the role of AWP.

15 MR. DODDS: Your Honor, I don't necessarily agree  
16 that that's the case, and I don't remember --

17 THE COURT: Did you see that? Who was the guy? He  
18 gave me -- he was standing there and there was the -- it was  
19 a great video.

20 MR. DODDS: Right. Your Honor, as I recall the  
21 tutorial, it dealt mainly with and most of the case up to  
22 that point in time dealt mainly with whether  
23 self-administered drugs were properly part of the case.  
24 That's really what your Honor labored with the most with  
25 respect to Track One.

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1 THE COURT: AWP is the sticker price, everybody  
2 knew that that was the industry benchmark. I mean, at this  
3 point I'm not changing that. Now, there may be another  
4 basis, there may be at some later point in time, but I  
5 certainly have plenty in the record, overwhelming evidence  
6 from both sides in the record that AWP is the typical way in  
7 which drugs were charged.

8 MR. DODDS: Your Honor, what I'm saying now, now we  
9 have a record of these individual Part B proffered class  
10 representatives, the individuals that have been proffered.

11 THE COURT: Right, and so with respect to the  
12 non-multi-source, as I understand it -- the Center for  
13 Medicare and Medicaid Services was here, the guy, the IT guy,  
14 who basically said, "I just have to throw in the name and I  
15 can tell you who the person is."

16 MR. DODDS: Can tell who the Medicare Part B  
17 beneficiaries are, yes.

18 THE COURT: Right. So I send out a notice to them,  
19 and if they paid out of their pocket, that's a damage issue.

20 MR. DODDS: Well, actually I take that back, your  
21 Honor. You can tell who the Medicare beneficiaries are who  
22 received a prescription drug under Medicare.

23 THE COURT: Sure, of that kind of whatever the  
24 brand name is.

25 MR. DODDS: Right, of a brand name. But, your

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1 Honor, as the evidentiary record that we have now shows, many  
2 of those people, and as Mr. Sobol acknowledged during that  
3 same hearing, a good four out of five of those people aren't  
4 going to have paid based on AWP at all.

5 THE COURT: Sure, and so they won't be able to  
6 claim.

7 MR. DODDS: And to find who the people are who can  
8 claim, you have to do a person-by-person analysis of their  
9 claims information, of what they received, of who they  
10 received it from, and of what they paid.

11 THE COURT: That's damages. Why isn't that  
12 damages?

13 MR. DODDS: Because, your Honor, unless they paid  
14 based on AWP, they're not within the class definition.

15 THE COURT: By definition, they do pay based on AWP  
16 because that's what the statute says, and that's why you have  
17 all conceded over time.

18 MR. DODDS: Your Honor, we've conceded that AWP,  
19 will confess, is a prominent feature of the reimbursement  
20 market. It is, there's no question about that. But under  
21 Medicare, it is not the case that every single individual who  
22 gets a drug under the Medicare benefit pays based on AWP. In  
23 fact --

24 THE COURT: I'm sure that's right, but that's  
25 atypical, and so -- or at least I haven't been persuaded that

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1 it's not typical. Let's just jump to the J-Code thing  
2 because that's confusing to me. So they've got a novel  
3 theory of standing which I haven't thought about before on  
4 the multi-source.

5 MR. DODDS: Before I do that, your Honor, and I  
6 will do that, but your Honor has asked us to sort of cut  
7 through the dense briefing, and just to make sure that you  
8 have a fair opportunity to think about the point that I've  
9 just made, which I understand is not a point that's pleasing  
10 to the Court at this point --

11 THE COURT: It's not that. It's a sea change.

12 MR. DODDS: It certainly is a point that hasn't  
13 been made up to this point, I understand that. I'm going to  
14 ask your Honor to go back and look at, as you look at the  
15 individual defendant's submissions, look at three cases that  
16 are cited in our brief.

17 THE COURT: Crosby?

18 MR. DODDS: One is the Crosby case, which says that  
19 you simply can't certify a class if to figure out who's in it  
20 you have to have individual fact-finding and litigation, and  
21 the record as to each of these defendants shows that's  
22 exactly what you have to do just to figure out who's in it.

23 The second case is the Sanneman case, which is an  
24 Eastern District of Pennsylvania case which deals with the  
25 same issue.

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1 THE COURT: It's for drugs?

2 MR. DODDS: No. None of these, your Honor, are  
3 cases that involve pharmaceutical products. The third case,  
4 your Honor, is a case called Dumas. I think these are all  
5 cited toward the end of our brief, which is an Eastern  
6 District --

7 THE COURT: Which footnote?

8 MR. DODDS: It's on Page 39. I don't remember  
9 which footnote, your Honor. And even with the glasses I've  
10 gotten since I was RICO man, I have trouble reading it too,  
11 but it's on Page 39, I believe.

12 Now, that was a case in which Mr. Sobol's firm  
13 represented the class, and I believe Mr. Sobol was involved  
14 in it. It didn't involve pharmaceutical products, but that  
15 was a case in which the court said, even if membership in the  
16 class as an objectively defined term -- in that case it was  
17 people who received counterfeit Lipitor -- in this case it's  
18 people who paid based on AWP -- the Court said that you  
19 cannot certify a class if to figure out who received  
20 counterfeit Lipitor you need to do a class-member-by-class-  
21 member analysis. And that's what you need to do here, as the  
22 record that you now have, that you didn't have before, shows.

23 THE COURT: Well, your expert is who, Young?

24 MR. DODDS: Young.

25 THE COURT: What percentage of people does he say

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1 don't get billed based on AWP?

2 MR. DODDS: I believe, your Honor, he breaks it  
3 down to there are only 9 percent make a co-pay out of pocket.

4 THE COURT: But that's a different question from  
5 what I just said. Yes, that's probably correct. That's  
6 consistent with what I've heard over time.

7 MR. DODDS: Correct.

8 THE COURT: Because for a variety of reasons. Many  
9 of them have supplemental insurance, which is Class 2.  
10 That's a primary reason. And the other is that sometimes the  
11 doctors don't charge people.

12 MR. DODDS: During the class period, that was  
13 common. In fact, now --

14 THE COURT: I understand that, but that's different  
15 from saying that AWP wasn't the benchmark used for the  
16 reimbursement scheme.

17 MR. DODDS: And, your Honor, I'm not claiming that  
18 there is nobody out there who paid based on AWP. I probably  
19 wasn't clear, but that's not what I'm saying. What I'm  
20 saying is, in order to find those people, in order to find  
21 those people, you need to do a very intensive  
22 person-by-person analysis, which the case law, Crosby in  
23 particular, says you can't do, you cannot certify a class  
24 under those circumstances.

25 THE COURT: I understand your point, but we have

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1 limited time, and I'm really struck with the new issue, which  
2 is for some reason it wasn't -- maybe I forgot about it or  
3 didn't focus on it, but it wasn't really vetted, is what to  
4 do with the multi-source drugs.

5 MR. DODDS: Yes, your Honor.

6 THE COURT: And that's a harder issue for me right  
7 now.

8 MR. DODDS: Right. And, your Honor, let me say  
9 that the fact that you have to do this analysis for  
10 multi-source drugs fits with the argument that I just made.  
11 The mere fact that you have to do it, under Crosby and the  
12 other cases I cited, says that you would be committing  
13 reversible error on this record to certify these classes.

14 THE COURT: Well, is it true as Mr. Sobol says that  
15 you can always figure out which person paid under a certain  
16 J-Code, but you can't then figure out which of the multiple  
17 sources the person actually purchased it from?

18 MR. DODDS: Correct. And in this instance, your  
19 Honor, it may be that they used a drug of a pharmaceutical  
20 company that's not even a defendant within this case, and  
21 there are individual briefs that make that point to you, that  
22 there are manufacturers of the drugs that have been placed in  
23 issue here that are not before you now. So on this sort of  
24 theoretical thing that you just heard about, which I'm not  
25 quite sure I follow, you would be creating a situation in

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1 which manufacturers who are before you could be held liable,  
2 if your Honor entertains all these notions, based on products  
3 that aren't even at issue here because of defendants that  
4 aren't even present here. That alone is reason enough to  
5 reject it, but that's a problem that's identified and made  
6 specific in certain of the specific defendant briefs.

7 THE COURT: Well, for the point of understanding  
8 whether someone is appropriately a class member or not,  
9 suppose you had a drug where all the sources were defendants,  
10 would that be a different situation where there was a  
11 significant number of companies that aren't defendants?

12 MR. DODDS: You know, your Honor, the answer is  
13 "no" because we're right back where we started back when I  
14 was RICO man, trying to find ways to avoid Article III  
15 standing. I don't know of any case, and defendants haven't  
16 cited any, where that requirement, that a defendant who wants  
17 to be a class representative here can simply avoid  
18 Article III standing based on some notion that sort of  
19 everybody contributed to it and everybody did it and they  
20 were injured by it. Article III standing is a threshold  
21 requirement that's glossed over by all of these theories that  
22 you've just heard about, all of which, your Honor, by the  
23 way, are after all this time purely theoretical. I mean,  
24 your Honor made the point that there's been extensive  
25 discovery at this point. There's been extensive discovery at

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1 this point, and think about what's happened up to this --

2 THE COURT: Is discovery closed for Track Two?

3 MR. DODDS: Yes, it is, your Honor. The discovery  
4 has been done. The work has been done. And think about  
5 what's happened up to this point in time. When the case  
6 started, your Honor found that the generic drugs, the  
7 multi-source drugs, didn't fit the paradigm and dismissed  
8 them. So they came back and they alleged that this  
9 leapfrogging was going on.

10 Now, Dr. Hartman talks about how it could happen.  
11 I'm not aware of any evidence that shows that it did happen,  
12 that there were any frogs or that there was any leaping,  
13 because if it did, you should be able to look in the Red Book  
14 or the Blue Book and see it. If my client Pharmacia -- all  
15 of our drugs are multi-source drugs -- if my client Pharmacia  
16 sets an AWP for a multi-source drug it has, and another  
17 defendant here decides that it wants to compete with that to  
18 raise the median, it should be a simple matter to read the  
19 read the Red Book, read book Blue Book, read the pricing  
20 publications and see it; but you've never been presented with  
21 any evidence that it happened because it simply didn't.

22 THE COURT: It's not clear to me why it happened,  
23 but let me ask you this, because it wouldn't help them  
24 competitively among each other. It didn't fit the paradigm  
25 as originally given to me, but regardless of why, what motive

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1 people had for putting a really high AWP if it didn't gain  
2 the market share, regardless of the motive, doesn't it  
3 similarly just hurt the consumer paying for it?

4 MR. DODDS: Your Honor, I suppose it could  
5 theoretically. The problem that you have here is, for  
6 purposes of class certification or for any other purpose, for  
7 that matter, you have no evidence to support any of the  
8 theories that have been presented here; not the leapfrogging,  
9 not the Nash equilibrium.

10 THE COURT: But what about, apart from all that, if  
11 under the statute an older person has a right to pay  
12 20 percent of AWP and it's inflated a thousand percent, isn't  
13 that person harmed?

14 MR. DODDS: I'm sorry, ask your question again,  
15 your Honor.

16 THE COURT: A lot of these people are older people,  
17 right, and they've got cancer?

18 MR. DODDS: Yes.

19 THE COURT: And they purchase a multi-source drug  
20 of a sort that they now can't figure out which company it  
21 was. Apart from why the AWP's were way up here, they  
22 nonetheless are overpaying for their copayment.

23 MR. DODDS: Your Honor, it depends on what the  
24 Medicare allowable is for that particular drug. Let me give  
25 you an example. Let me give you the example that has been

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1 given for my client, Pharmacia, okay. One of the class reps  
2 that's been presented for Pharmacia is the estate of  
3 Mrs. Young, and the drug that she supposedly took, allegedly  
4 took, was a drug called SoluCortef, which is a multi-source  
5 drug that is manufactured by many defendants, some of whom  
6 are here, some of whom are not here.

7 Now, our papers talk about whether they can  
8 identify that as our drug, okay, and so I won't belabor  
9 that. But if you look at Mr. Haviland's declaration with  
10 respect to Mrs. Young, you see a bunch of claims information  
11 that shows, here's how much the doctor billed, here's the  
12 Medicare allowable, which was way below what the doctor  
13 billed, here's what the insurer paid --

14 THE COURT: When you say "billed," billed who?

15 MR. DODDS: What the doctor billed for the services  
16 that were provided.

17 THE COURT: To Medicare?

18 MR. DODDS: Correct, what the doctor billed to  
19 Medicare and what the doctor billed to -- well, in this case,  
20 what the doctor billed to the insurers, which were Medicare,  
21 and then there's a supplemental insurer.

22 THE COURT: All right, and Mrs. Young didn't pay  
23 anything?

24 MR. DODDS: Mrs. Young was ultimately billed, I  
25 believe, 31 cents for the first administration and, like,